

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in August 2013.

### Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### ANADA Number: 200-524

Trade Name: Mupirocin Ointment 2%  
Pioneer: Bactoderm® Ointment  
Ingredients: Mupirocin  
Sponsor: Putney, Inc.  
Approval Date: June 24, 2013  
Status: Rx  
Route: Topical  
Species: Dogs  
Drug Form: Ointment  
Concentration: 2% (20 mg/g)  
Indications: For the topical treatment of canine bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

21 CFR 524.1465

78 FR 52852-52854

#### ANADA Number: 200-517

Trade Name: Zobuxa™  
Pioneer: Baytril® Antibacterial Tablets  
Ingredients: Enrofloxacin  
Sponsor: Novartis Animal Health US, Inc.  
Approval Date: June 20, 2013  
Status: Rx  
Route: Oral  
Species: Cats and dogs  
Drug Form: Tablet  
Concentration: 22.7 mg, 68 mg, 136 mg, and 272 mg  
Indications: For the management of diseases associated with bacteria susceptible to enrofloxacin.

21 CFR 520.812

78 FR 52852-52854

#### ANADA Number: 200-519

Trade Name: Florvio™ 2.3% Concentrate Solution  
Pioneer: Nuflor® Concentrate Solution  
Ingredients: Florfenicol  
Sponsor: Novartis Animal Health US, Inc.  
Approval Date: May 23, 2013  
Status: Rx  
Route: Oral  
Species: Swine  
Drug Form: Oral concentrate solution  
Concentration: 23 mg florfenicol/mL  
Indications: For the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis* in swine.

21 CFR 520.995

78 FR 52852-52854

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### ANADA Number: 200-547

Trade Name: Zilmax® plus Rumensin® plus Tylovet® 100  
Pioneer: Zilmax® plus Rumensin® plus Tylan®  
Ingredients: Zilpaterol hydrochloride plus monensin USP plus tylosin phosphate  
Sponsor: Huvepharma AD  
Approval Date: June 25, 2013  
Status: OTC  
Route: Oral, in feed  
Species: Cattle fed in confinement for slaughter  
Drug Form: Type A medicated articles  
Concentration: Zilpaterol hydrochloride – 21.77 g/lb  
Monensin USP – 80 g/lb  
Tylosin phosphate – 40 and 100 g/lb  
Indications: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle fed in confinement for slaughter for the last 20 to 40 days on feed.

21 CFR 558.665

78 FR 52852-52854

### ANADA Number: 200-555

Trade Name: Librevia™  
Pioneer: Rimadyl® Chewable Tablets  
Ingredients: Carprofen  
Sponsor: Piedmont Animal Health  
Approval Date: June 13, 2013  
Status: RX  
Route: Oral  
Species: Dogs  
Drug Form: Soft Chewable Tablet  
Concentration: 25, 75, and 100 mg  
Indications: For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

21 CFR 520.309

78 FR 52852-52854

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## Withdrawal of Approval

### NADA Number: 098-371

Sponsor: Phibro Animal Health Corp.  
Trade Name: Nicarbazin plus penicillin plus roxarsone  
Ingredients: Nicarbazin, penicillin, roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.366

78 FR 52429-52430

### NADA Number: 098-374

Sponsor: Phibro Animal Health Corp.  
Trade Name: Nicarbazin plus penicillin  
Ingredients: Nicarbazin, penicillin

This product is withdrawn because the product is no longer manufactured or marketed.

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21 CFR 558.460

78 FR 52429-52430

### NADA Number: 123-116

Sponsor: R. P. Scherer North America  
Trade Name: Diethylcarbamazine Citrate Capsules  
Ingredients: Diethylcarbamazine citrate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.622d

78 FR 52429-52430

### NADA Number: 097-980

Sponsor: Quali-Tech Products, Inc.  
Trade Name: Quali-Tech Tylan®-10 Premix  
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.625

78 FR 52430-52431

### NADA Number: 118-815

Sponsor: Quali-Tech Products, Inc.  
Trade Name: Q.T. Ban-Tech  
Ingredients: Pyrantel Tartrate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.485

78 FR 52430-52431

### NADA Number: 132-705

Sponsor: Quali-Tech Products, Inc.  
Trade Name: Flavomycin®  
Ingredients: Bambermycins

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.95

78 FR 52430-52431

### NADA Number: 133-335

Sponsor: Quali-Tech Products, Inc.  
Trade Name: Stafac® Swine Pak 10 g  
Ingredients: Virginiamycin

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.635

78 FR 52430-52431